DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

9/26/01

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 2951064

May 14, 2001

E. Manuel Costa, Owner
C & C Holsteins
13243 Houston Avenue
Hanford, California 93230

WARNING LETTER

Dear Mr. Costa:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on April 20 and 23, 2001 by the Food and Drug Administration (FDA) have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On February 19, 2001, you consigned a cow, identified with back tag number 93 EZ 9856 (USDA laboratory report number 419005), for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of the drug penicillin in the kidney at 0.59 parts per million (ppm). The tolerance has been established for residues of penicillin in the edible tissues of cattle at 0.05 ppm.

Your firm has established a history of offering animals for sale for human food which have been found to be adulterated due to the presence of drug residues. According to USDA analytical report 281446, dated January 13, 2000, your firm offered a cow for sale with illegal residues of penicillin. USDA analytical report 408734, dated June 6, 2000 reported that you offered for sale another cow that also contained illegal residues of penicillin. In addition, our records show that between July 1993 and January 1996 you offered for sale five (5) other animals that contained illegal drug residues.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful

drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter. Your medication records do not contain all drugs and dosages administered and do not identify the individual performing the medication of each animal at your dairy.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling or your veterinarian's prescription labeling.

You are adulterating the drug Agri-Cillin brand penicillin G procaine within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) of the Act and it is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. Agri-Cillin's labeling prescribes a dosage of 1 ml per 100 pounds of body weight with the drug to be administered by the intramuscular route. Your practice of administering 30 mL per day results in a dosage in excess of that allowed by the labeling. Additionally, your practice of mixing 30 mLs of the Agri-Cillin brand penicillin G procaine injection with 30 mLs of water to prepare a uterine infusion to medicate your lactating cattle is an unapproved use for which safety and efficacy has not been established and requires the submission of a New Animal Drug Application for FDA approval. Failure to follow the approved labeling is the likely cause of the illegal drug residues found in the animal you sold for slaughter.

Failure to comply with the label instructions on drugs you use to treat your cows and calves presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it

was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Russell A. Campbell, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

Dennis K. Linsley
District Director

cc: [redacted]